Revision ratio after Femoral Neck System implantation for hip fracture treatment: a retrospective cohort analysis

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The aim of the study is to determine the revision ratio after implantation of the femoral neck system (FNS) for the treatment of femoral neck fractures. A retrospective single center cohort analysis with a total of 71 patients who underwent the implantation of the FNS between December 2019 and December 2021, was performed. 31 males and 40 females were included. There was no exclusion based on BMI, ASA score, Garden classification or Pauwels classification. Primary outcome was the revision rate after FNS implantation. Secondary outcomes comprise the reason for revision surgery as well as the time toward revision surgery and the 30-day mortality. The revision ratio was 11 out of 71 patients (15.5%) with an average time to revision surgery of 10 months. Most common reason for revision was avascular necrosis (AVN) in 45.5%. Other reasons for revision surgery were implant failure due to a secondary fall on to the hip with the FNS implant in place, cut-out, cut-through and malunion in respectively 27.3%, 9%, 9% and 9% of the revision patients. The one-hole plate was used in 72% of the patients. Partial weight bearing in 14.1% of the patients. In conclusion, the FNS has similar revision ratio when used for femoral neck fractures compared to cannulated screw fixation in literature. The predominant reason for revision is AVN and implant failure with no difference between the use of the one- or-two-hole plate in this study.

Keywords: Femoral neck system, Femoral neck fractures, hip fracture, internal fixation.

INTRODUCTION

Femoral neck fractures (FNF) are one of the most frequent fractures in the middle and older aged population¹. These fractures are associated with high morbidity, mortality and economic burden. Increased age is an important predicting factor for FNF. As life expectancy is increasing, the risk of osteoporotic fragility fractures rises with it. In recent years, there is a tendency of expanding the indication for osteosynthesis toward older aged patients (>65years) in which stabilization of this type of fractures by osteosynthesis instead of hip replacement surgery can be the preferred treatment, as it is in the younger population²⁻⁴. This stresses the importance of the use of adequate implants for fracture fixation with minimal risk of revision surgery.

The femoral neck is known to have a precarious vascular supply by its circumflex vessels, branches of the arteria profunda femoris. The medial circumflex artery has the greatest contribution to the femoral head (82%) and neck's (67%) blood supply⁵. In non-

or minimally displaced femoral fractures there is a chance of fractures healing instead of an evolution towards avascular necrosis when the blood supply is not compromised⁵⁻⁷. Avascular necrosis rates after FNF are between 6-23% in current literature⁷⁻⁹. Other complications are non-union, malunion and implant failure. Revision surgery after FNF remains high in literature with conventional methods (cannulated screw fixation, dynamic hip screw, a.o.). Revision surgery is necessary in about 20% (15-38%) of the cases after FNF fixation^{3,10-12}.

If the life expectancy of the patient is longer than current hip prosthesis survival, osteosynthesis is preferred. Cannulated screw fixation is assumed to be the golden standard for FNF. However, in recent years, several new implant systems have been developed to address this type of fractures. One of them is the Femoral Neck System (FNS ©Depuy Synthes). Recently, the tendency toward primary total hip arthroplasty in young patients is rising. Although the revision rates are lower, these operations are associated with increased cost, length of stay and complications¹¹.



Fig. 1. — Pre-operative and post-operative radiographic image. (A) AP view of a valgus impacted femoral neck fracture. (B) AP view of the same fractured hip after the placement of the FNS (Femoral Neck System) implant.

The need for reliable implants for osteosynthesis with a predictable outcome and minimal risk for revision surgery is paramount to deal with these fractures.

The FNS is an implant first released in 2018 and is produced by Depuy Synthes (a part of the Johnson and Johnson company). It can be used for FNF fixation (Fig. 1). This implant provides multiple advantages such as angular and rotational stability and decreased risk in compromising the vascular blood supply in the femoral head. Furthermore, it can give compression at the fracture site if dynamized during implantation (Fig. 2). It seems to have better resistance toward femoral neck shortening and even improved fracture healing time compared to cannulated screws. Lastly, this implant has the tendency of improving the functional outcomes in recent literature¹³.

To our best knowledge the revision ratio after FNS implantation is never investigated as a primary outcome parameter in current literature. As this is a relatively new implant, we tend to do a retrospective cohort study on the revision ratio after implantation of this implant.

METHODS

This retrospective cohort study was conducted after ethical approvement was granted by the hospital's Ethical Committee. The primary outcome was the revision rate after FNS implantation in patients with femoral neck fractures. Secondary outcomes were the reasons for revision, time until revision surgery and the 30-day mortality.

Inclusion criteria consisted of all patients who underwent osteosynthesis using the FNS system between December 2019 and December 2021. Both

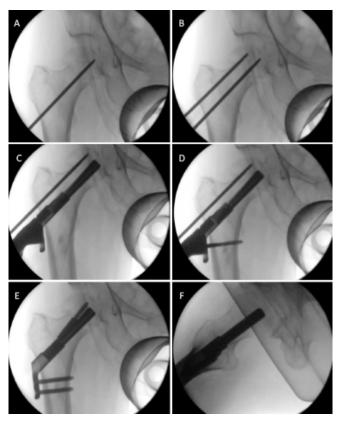


Fig. 2. — Intra-operative radiographic images of the FNS (Femoral Neck System) implantation. (A) AP view insertion of the guide-wire into the head of the femur. (B) Placement of an antirotation K-wire. (C) Insertion of the FNS implant after pre-drilling. (D) Predrilling of the locking screws. (E) FNS implant after the insertion of the antirotation screw. (F) Lateral view of the hip after full FNS implantation.

men and women were included. Garden types I, II, III and IV and Pauwels types I, II and III were included. There was no exclusion based on age, body mass index, comorbidities and ASA score (ASA I-IV eligible). Patients with pathological fractures, multifocal fractures in the femur or polytrauma patients were excluded.

All patient reports were checked retrospectively to verify if there was the need for revision surgery in the post-operative period. Patients were contacted by phone to ensure there was no revision surgery at the FNS implanted hip, performed in another institute. Family members were contacted, if the patient already died in the post-operative period, to ensure there was no need for revision surgery.

Implant specification as one-or two-hole plate and post-operative instructions toward weight bearing were checked in de patient reports. Weight bearing was subdivided in full weight bearing, partial weight bearing and non-weight bearing. The length of stay and radiographic tip apex distance were calculated. The

| | | Number of patients | % |
|------------------------|--------|--------------------|-------|
| Total | | 71 | |
| Age at surgery | | 69.47 [±15.69] * | |
| average BMI | | 24.34 [±4.81] ** | |
| Gender | male | 31 | 43.6% |
| | female | 40 | 56.3% |
| ASA-score | III | 27 | 38.0% |
| | II | 19 | 26.7% |
| | Ι | 22 | 30.9% |
| Garden classification | Ι | 28 | 39.4% |
| | II | 30 | 42.3% |
| | III | 9 | 12.6% |
| | IV | 0 | 0.00% |
| Pauwels classification | Ι | 20 | 28.1% |
| | II | 38 | 53.5% |
| | III | 13 | 18.3% |
| Holes in plate | 1 | 51 | 71.8% |
| | 2 | 20 | 28.1% |

Table I. — Demographic data

tip apex distance was assumed to be optimal around 20mm ($20\pm2\text{mm}$) and was calculated on the postoperative radiography on day one after the surgery. 30-day mortality was calculated as well. The reason for revision, time to revision and follow-up were determined.

Data collection was conducted using the patient reports by two individual investigators. Basic statistical tests were performed using SPSS version 28. Descriptive data are presented as means and standard deviations. The Fisher exact statistical test was used to calculate statistical difference between categorical data. A P-value less than 0.05 was considered statistically significant.

RESULTS

A total of 71 patients were included. The mean age at surgery was 69,5 years [$\pm 15,69$]. There were 31 (44%) males and 40 (56%) females included. Most of the fractures were classified as Garden II (30/71, 42%) and Garden I (28/21, 39%). There were no patients with Garden IV fractures. A Pauwels type II fracture was present in 54% of the patients and was the main

fracture pattern. Pauwels I and III were respectively present in 28% (20/71) and 18% (13/71) of the patients. Most of the patients had multiple morbidities and were classified with ASA score III (38%) (Table I).

Of the 71 patients that were treated with the FNS system, 11 (15.5%) patients needed revision surgery for a variety of reasons. The average time to revision surgery was 10.0 months. Avascular necrosis was the main reason for revision and developed in 7% of the patients (5/71) and was therefore responsible for 45.5%(5/11) of the revisions with a mean time to surgery of 19 months (10-27,4 months). Cut-out of the implant occurred in one (1/71) patient and cut-through occurred in two patients (2/71). The latter were responsible for respectively 9% and 18.2% of the revisions. In one patient, there was a minimal cut-through on the postoperative radiography the day after surgery. However, this patient had no complaints and required no further revision surgery within a 23 month follow-up and was therefore not included in the calculations for patients with revision surgery. Three (3/71, 4.2%) patients had a secondary fall on to the hip with the FNS implant with breakout of the implant and the need for revision surgery. This was responsible for 27.3% (3/11) of the

| | Number of patients | % (n=71) | | | |
|---|--------------------|-------------|--|--|--|
| AVN | 5 | 7% | | | |
| Secondary fall on hip | 3 | 4.2% | | | |
| Cut-out | 1 | 1.4% | | | |
| Cut-through | 1 | 1.4% | | | |
| Malunion | 1 | 1.4% | | | |
| Infection | 0 | 0% | | | |
| Hematoma | 0 | 0% | | | |
| | 11 | 15.5% | | | |
| Reasons for revision surgery subdivided into avascular necrosis | | | | | |

Table II. — Revisions

Reasons for revision surgery subdivided into avascular necrosis of the femorale head (AVN), secondary fall on hip, cut-out and cut-through and malunion as number of patients and as percentage (with a total of 71 patients).

Table III. — Secondary outcomes

| | | Number of patients | f | % (n=71) | | |
|---|---------|--------------------|---------------|-------------|--|--|
| Weight bearing | No | 0 | | 0% | | |
| | Partial | 10 | | 14.1% | | |
| | Full | 61 | | 85.9% | | |
| 30-day mortality | no | 69 | | 97.2% | | |
| | yes | 2 | | 2.8% | | |
| Mortality during follow-up | | 9 | | 12.6% | | |
| | | Months | | Range | | |
| Average follow-up | | 18.07 | | [6-30]* | | |
| Average time to revision surgery | | 10.6 | [0.03-24.8]** | | | |
| *presenting the average follow-up range in months. ** pre- senting the average time to revision surgery range in months. | | | | | | |

revisions. One patient had a malunion with femoral neck shortening and required revision surgery (1/71) and was responsible for 9% of the revisions. There was no revision due to infection or post-operative bleeding (Table II).

The 30-day mortality was two out of the 71 patients (2.8%). These patients had a mean age of 88,5 years. 9 (12.7%) patients died during the entire follow-up period. These 9 patients had a mean age of 78,11 years. None of these deaths were due to a post-operative complication. The average duration of follow-up of the total population was 18,07 months with a minimum of 6 months. 23.9% (17/71) of the patients had a follow-

up less than 12 months. The longest follow-up of a patient was 30 months (Table III).

85.9% (61/71) of the patients had the post-operative instruction to fully bear their weight on the operated side. 14.1% were only allowed to partially bear weight due to poor bone quality. There were no patients who had non-weight bearing instructions (Table III).

Mean length of stay (LOS) was 8,74 (\pm 8,45) days. However, if the LOS was calculated for the patients less than 70 years of age (32/71) this was only 3,9 days. The one-hole plate was predominantly used (72% versus 28%). The mean age was slightly younger in the group of patients where a one-hole plate was used (68,8 years vs. 71,2 years). There was no difference in ASA score, Pauwels classification or Garden classification between the one- or two-hole groups. Revision ratio between the one-hole plate group and the two-hole plate group was not different as well (p=0.491).

The tip apex distance (TAD) could be calculated correctly in the post-operative radiographs in 65 patients. The average TIP apex distance after the implantation was 24,13 mm. In this subgroup, there was no difference in revision ratio (6/50 vs 2/15) between the placement of the bolt with a TAD between 18-22mm and patients with a TAD outside the assumed optimal range (p=0.597).

DISCUSSION

This study showed a revision ratio after FNS implantation of 15.5%. Notwithstanding the scarcity of studies about this topic, these findings are in accordance with the recent study of Schuetze et al. on 113 FNS patients. In their study there was the need for revision surgery in 13.3% of the patients. They had a comparable population with similar mean age of 69.5 years and inclusion criteria. However, the main reason for revision surgery in their study was cut-out in 14 patients. In our study there were only 5 (7%, 5/71) implant related revisions (cut-out, cut-through and break-out due to secondary fall).

The rate of implant failure due to AVN was comparable in this FNS population (7%) compared to cannulated screw fixation in the study of Kain M. et al. (6%, N=121) and Loizou C.L. et al. (6,6%, N=1023)^{8,9}. In the study of Schuetze et al. and Tang et al. avascular necrosis was the reason for revision in respectively 0% and 2% of the cases^{13,14}. However, they had a mean follow-up of 13 months and a range of 14-24 months respectively. They were therefore limited in the detection of avascular necrosis as a complication. The mean time for detection and revision surgery for AVN

in our population was 19 months ranging from 10 to 27,4 months after the FNS implantation.

In our study we have a mean follow-up of 18.07 months with a minimum follow-up of 6 months and a maximum of 30 months. In current literature there is a lack of studies with a follow-up longer than 12 months. To our best knowledge we presented the longest follow-up in current literature. As the mean time towards AVN was 19 months in our study, this could be the reason for underestimation of the number of AVN in other studies.

The most femoral neck fractures occur due to vertical forces on the hip or direct impact on the greater trochanteric region¹⁵. In young people the likelihood of breaking the hip at the femoral neck is much higher than at the trochanteric region. In this population, these fractures are therefore more vertically orientated. This requires more stability to compensate for the displacing forces and is another factor that influences the risk of implant failure. In our FNS population the number of Pauwels type II and III was respectively 53.5% (38/71) and 18.3% (13/71). The study of. Zhirong Fan et al. suggested that in a FNF with angulation of the fracture above 70 degrees (Pauwels III), a two hole plate is preferred and under 60 degrees the onehole plate suffice¹⁶. In our study, 38.5% (5/13) of the Pauwels III fractures had a two-hole plate. The choice of one-or two-hole plate was decided by the surgeon's preferences and not determined by fracture angulation.

In 3 out of the 4 revisions in this Pauwels III group a one-hole plate was used. In only one of the three patients with a one-hole plate there was the need for revision surgery due to a cut-out. We cannot attribute the failure solely to the usage of one- or two-holes as the tip apex distance was also not within the assumed optimal range and could be a contributing factor for implant failure. Moreover, the calculation considering this matter was based on small numbers and could therefore lack power to detect any difference. However, the study of Schuetze K. et al (N=103) confirmed the findings of Zhirong Fan et al. on the increased failure rate with the use of a one-hole plate in Pauwels III fracture patterns¹⁴.

As mentioned, the TAD is a contributing factor that influences the risk of implant failure. The length of the bolt and therefore the tip apex distance is important for the stability. In the biomechanical study of C-H Jung et al., their finite element analysis in Pauwels type III FNF demonstrated an increased stability with subchondral placement of the implant¹⁷. If the TAD increases, the risk of implant failure increases with it. In our study we had 18.2% (2/11) implant failure due to cut-out and cut-through. Our average TAD was 24,13mm. However, the importance of the TAD and optimal range is not yet investigated in clinical studies specifically for the FNS as it is for the dynamic hip screw (DHS) placement. Notwithstanding, the assumption is that it is as important for the FNS system as it is for the DHS and intramedullary nailing based on the study of C-H Jung et al. In our population, only two of the three patients with implant failure due to a cut-out or cut-through, the TAD could be correctly measured in the post-op radiography and was increased (mean 29.5 mm) compared to the patient without breakout (mean 23.9mm), however this finding was not statistically significant (p=0.360).

The limitations of this study are the absence of a control group and the retrospective design. The followup was at least 6 months, however the appearance of symptomatic and radiographic features of avascular necrosis can be longer than 6 months. There were 17 patients (23.9%) with a follow-up less than 12 months. In this group there is the probability of subclinical avascular necrosis or other cause that will necessitate a secondary intervention, later-on. This underestimates the revision ratio. Furthermore, only complications that required reintervention were investigated. Lastly, this was a multi-surgeon study, which makes our results more prone to inter-surgeon viability.

CONCLUSION

The FNS implant is a safe and reliable implant on behalf of the presented outcomes when used in the right population with a FNF with minimal displacement, if taking in account the biomechanical properties and proper implantation instructions. In this retrospective cohort analysis with the longest follow-up in current literature, the revision ratio is in the same order as described in literature for cannulated screw fixation. We could not find any difference between the oneor two-hole plate on behalf of the need for revision surgery, nor any significant relation with the Pauwels classification.

Conflict of interest: The authors declare to have no conflicts of interest.

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Data interpretation: SA and LJM Drafting manuscript: LJM and SA Revising manuscr. J Bone Min Res. 2014;29(3):581-9.

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